DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 24 1998

Re: BeneFIX™
Docket No.: 97E-0168

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 5,171,569, filed by British Technology Group Limited, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for BeneFIX™, the human biological product claimed by the patent.

The total length of the regulatory review period for BeneFIX™ is 749 days. Of this time, 583 days occurred during the testing phase and 166 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 26, 1995.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on January 26, 1995.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: August 30, 1996.

   The applicant claims August 29, 1996, as the date the Product License Application (PLA) for BeneFIX™ (PLA 96-1048) was initially submitted. However, FDA records indicate that PLA 96-1048 was submitted on August 30, 1996.

3. The date the application was approved: February 11, 1997.

   FDA has verified the applicant's claim that PLA 96-1048 was approved on February 11, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: M.C. Meinert, Esq.
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